(A) the chemical substance or mixture with respect to which such application was submitted is equivalent to a chemical substance or mixture for which ~~data~~ information has been submitted to the Administrator in accordance with a rule, order, or consent agreement under subsection (a) or for which ~~data~~ information is being developed pursuant to such a rule, order, or consent agreement, and

(B) submission of ~~data~~information by the applicant on such substance or mixture would be duplicative of ~~data~~information which has been submitted to the Administrator in accordance with such rule, order, or consent agreement or which is being developed pursuant to such rule, order, or consent agreement,

the Administrator shall exempt, in accordance with paragraph (3) or (4), the applicant from conducting tests and submitting ~~data~~information on such substance or mixture under the rule or order with respect to which such application was submitted.

(3) (A) If the exemption under paragraph (2) of any person from the requirement to conduct tests and submit ~~test data~~information on a chemical substance or mixture is granted on the basis of the existence of previously submitted ~~test data~~information and if such exemption is granted during the reimbursement period for such ~~test data~~information (as prescribed by subparagraph (B)), then (unless such person and the persons referred to in clauses (i) and (ii) agree on the amount and method of reimbursement) the Administrator shall order the person granted the exemption to provide fair and equitable reimbursement (in an amount determined under rules of the Administrator)—

(i) to the person who previously submitted such ~~test data~~information, for a portion of the costs incurred by such person in complying with the requirement to submit such ~~data~~information, and

(ii) to any other person who has been required under this subparagraph to contribute with respect to such costs, for a portion of the amount such person was required to contribute.

In promulgating rules for the determination of fair and equitable reimbursement to the persons described in clauses (i) and (ii) for costs incurred with respect to a chemical substance or mixture, the Administrator shall, after consultation with the Attorney General and the Federal Trade Commission, consider all relevant factors, including the effect on the competitive position of the person required to provide reimbursement in relation to the person to be reimbursed and the share of the market for such substance or mixture of the person required to provide reimbursement in relation to the share of such market of the persons to be reimbursed. An order under this subparagraph shall, for purposes of judicial review, be considered final agency action.

(B) For purposes of subparagraph (A), the reimbursement period for any ~~test data~~information for a chemical substance or mixture is a period—

(i) beginning on the date such ~~data~~information is submitted in accordance with a rule, order, or consent agreement ~~promulgated~~ under subsection (a), and

(ii) ending—

(I) five years after the date referred to in clause (i), or

(II) at the expiration of a period which begins on the date referred to in clause (i) and which is equal to the period which the Administrator determines was necessary to develop such ~~data~~information,

whichever is later.

(4) (A) If the exemption under paragraph (2) of any person from the requirement to conduct tests and submit ~~test data~~information on a chemical substance or mixture is granted on the basis of the fact that ~~test data~~information is being developed by one or more persons pursuant to a rule, order, or consent agreement ~~promulgated~~ under subsection (a), then (unless such person and the persons referred to in clauses (i) and (ii) agree on the amount and method of reimbursement) the Administrator shall order the person granted the exemption to provide fair and equitable reimbursement (in an amount determined under rules of the Administrator)—

(i) to each such person who is developing such ~~test data~~information, for a portion of the costs incurred by each such person in complying with such rule, order, or consent agreement, and

(ii) to any other person who has been required under this subparagraph to contribute with respect to the costs of complying with such rule, order, or consent agreement, for a portion of the amount such person was required to contribute.

In promulgating rules for the determination of fair and equitable reimbursement to the persons described in clauses (i) and (ii) for costs incurred with respect to a chemical substance or mixture, the Administrator shall, after consultation with the Attorney General and the Federal Trade Commission, consider the factors described in the second sentence of paragraph (3)(A). An order under this subparagraph shall, for purposes of judicial review, be considered final agency action.

(B) If any exemption is granted under paragraph (2) on the basis of the fact that one or more persons are developing ~~test data~~information pursuant to a rule, order, or consent agreement ~~promulgated~~ under subsection (a) and if after such exemption is granted the Administrator determines that no such person has complied with such rule, order, or consent agreement, the Administrator shall (i) after providing written notice to the person who holds such exemption and an opportunity for a hearing, by order terminate such exemption, and (ii) notify in writing such person of the requirements of the rule or order with respect to which such exemption was granted.

(d) NOTICE.—Upon the receipt of any ~~test data~~information pursuant to a rule, order, or consent agreement under subsection (a), the Administrator shall publish a notice of the receipt of such ~~data~~information in the Federal Register within 15 days of its receipt. Subject to section 14 [*15 U.S.C. § 2613*], each such notice shall (1) identify the chemical substance or mixture for which ~~data~~information ~~have~~has been received; (2) list the uses or intended uses of such substance or mixture and the information required by the applicable ~~standards~~protocols and methodologies for the development of ~~test data~~information; and (3) describe the nature of the ~~test data~~information developed. Except as otherwise provided in section 14 [*15 U.S.C. § 2613*], such ~~data~~information shall be made available by the Administrator for examination by any person.

(e) PRIORITY LIST.—

(1) (A) There is established a committee to make recommendations to the Administrator respecting the chemical substances and mixtures to which the Administrator should give priority consideration for the ~~promulgation~~development of ~~a rule~~information under subsection (a). In making such a recommendation with respect to any chemical substance or mixture, the committee shall consider all relevant factors, including—

(i) the quantities in which the substance or mixture is or will be manufactured,
(ii) the quantities in which the substance or mixture enters or will enter the environment,
(iii) the number of individuals who are or will be exposed to the substance or mixture in their places of employment and the duration of such exposure,
(iv) the extent to which human beings are or will be exposed to the substance or mixture,
(v) the extent to which the substance or mixture is closely related to a chemical substance or mixture which is known to present an unreasonable risk of injury to health or the environment,
(vi) the existence of ~~data~~information concerning the effects of the substance or mixture on health or the environment,
(vii) the extent to which testing of the substance or mixture may result in the development of ~~data~~information upon which the effects of the substance or mixture on health or the environment can reasonably be determined or predicted, and
(viii) the reasonably foreseeable availability of facilities and personnel for performing testing on the substance or mixture.

The recommendations of the committee shall be in the form of a list of chemical substances and mixtures which shall be set forth, either by individual substance or mixture or by groups of substances or mixtures, in the order in which the committee determines the Administrator should take action under subsection (a) with respect to the substances and mixtures. In establishing such list, the committee shall give priority attention to those chemical substances and mixtures which are known to cause or contribute to or which are suspected of causing or contributing to cancer, gene mutations, or birth defects. The committee shall designate chemical substances and mixtures on the list with respect to which the committee determines the Administrator should, within 12 months of the date on which such substances and mixtures are first designated, initiate a proceeding under subsection (a). The total number of chemical substances and mixtures on the list which are designated under the preceding sentence may not, at any time, exceed 50.

(B) As soon as practicable but not later than nine months after the effective date of this Act [*15 U.S.C. § 2601* effective date note], the committee shall publish in the Federal Register and transmit to the Administrator the list and designations required by subparagraph (A) together with the reasons for the committee's inclusion of each chemical substance or mixture on the list. At least every six months after the date of the transmission to the Administrator of the list pursuant to the preceeding [preceding] sentence, the committee shall make such revisions in the list as it determines to be necessary and shall transmit them to the Administrator together with the committee's reasons for the revisions. Upon receipt of any such revision, the Administrator shall publish in the Federal Register the list with such revision, the reasons for such revision, and the designations made under subparagraph (A). The Administrator shall provide reasonable opportunity to any interested person to file with the Administrator written comments on the committee's list, any revision of such list by the committee, and designations made by the committee, and shall make such comments available to the public. Within the 12-month period beginning on the date of the first inclusion on the list of a chemical substance or mixture designated by the committee under subparagraph (A) the Administrator shall with respect to such chemical substance or mixture ~~either initiate a rulemaking proceeding under subsection (a) or if such a proceeding is not initiated within such period, publish in the Federal Register the Administrator's reason for not initiating such a proceeding~~issue an order, enter into a consent agreement, or initiate a

rulemaking proceeding under subsection (a), or, if such an order or consent agreement is not issued or such a proceeding is not initiated within such period, publish in the Federal Register the Administrator's reason for not issuing such an order, entering into such a consent agreement, or initiating such a proceeding.

(2) (A) The committee established by paragraph (1)(A) shall consist of ~~eight~~ten members as follows:

(i) One member appointed by the Administrator from the Environmental Protection Agency.

(ii) One member appointed by the Secretary of Labor from officers or employees of the Department of Labor engaged in the Secretary's activities under the Occupational Safety and Health Act of 1970.

(iii) One member appointed by the Chairman of the Council on Environmental Quality from the Council or its officers or employees.

(iv) One member appointed by the Director of the National Institute for Occupational Safety and Health from officers or employees of the Institute.

(v) One member appointed by the Director of the National Institute of Environmental Health Sciences from officers or employees of the Institute.

(vi) One member appointed by the Director of the National Cancer Institute from officers or employees of the Institute.

(vii) One member appointed by the Director of the National Science Foundation from officers or employees of the Foundation.

(viii) One member appointed by the Secretary of Commerce from officers or employees of the Department of Commerce.

(ix) One member appointed by the Chairman of the Consumer Product Safety Commission from Commissioners or employees of the Commission.

(x) One member appointed by the Commissioner of Food and Drugs from employees of the Food and Drug Administration.

(B) (i) An appointed member may designate an individual to serve on the committee on the member's behalf. Such a designation may be made only with the approval of the applicable appointing authority and only if the individual is from the entity from which the member was appointed.

(ii) No individual may serve as a member of the committee for more than four years in the aggregate. If any member of the committee leaves the entity from which the member was appointed, such member may not continue as a member of the committee, and the member's position shall be considered to be vacant. A vacancy in the committee shall be filled in the same manner in which the original appointment was made.

(iii) Initial appointments to the committee shall be made not later than the 60th day after the effective date of this Act [*15 U.S.C. § 2601* effective date note]. Not later than the 90th day after such date the members of the committee shall hold a meeting for the selection of a chairperson from among their number.

(C) (i) No member of the committee, or designee of such member, shall accept employment or compensation from any person subject to any requirement of this Act [*15 U.S.C. §§ 2601* et seq.] or of any rule promulgated or order issued thereunder, for a period of at least 12 months after termination of service on the committee.

(ii) No person, while serving as a member of the committee, or designee of such member, may own any stocks or bonds, or have any pecuniary interest, of substantial value in any person engaged in the manufacture, processing, or distribution in commerce of any chemical substance or mixture subject to any requirement of this Act [*15 U.S.C. §§ 2601* et seq.] or of any rule promulgated or order issued thereunder.

(iii) The Administrator, acting through attorneys of the Environmental Protection Agency, or the Attorney General may bring an action in the appropriate district court of the United States to restrain any violation of this subparagraph.

(D) The Administrator shall provide the committee such administrative support services as may be necessary to enable the committee to carry out its function under this subsection.

(f) REQUIRED ACTIONS.—Upon the receipt of—

(1) any ~~test data~~information required to be submitted under this Act [*15 U.S.C. §§ 2601* et seq.], or

(2) any other information available to the Administrator,

which indicates to the Administrator that there may be a reasonable basis to conclude that a chemical substance or mixture presents ~~or will present~~ a significant risk of serious or widespread harm to human beings ~~from cancer, gene mutations, or birth defects~~, the Administrator shall, within the 180-day period beginning on the date of the receipt of such ~~data or~~ information, initiate ~~appropriate~~applicable action under section 5, 6, or 7 [*15 U.S.C. § 2604*, *2605*, or *2606*] to prevent or reduce to a sufficient extent such risk or publish in the Federal Register a finding made without consideration of costs or other nonrisk factors that such risk is not unreasonable. For good cause shown the Administrator may extend such period for an additional period of not more than 90 days. The Administrator shall publish in the Federal Register notice of any such extension and the reasons therefor. A finding by the Administrator that a risk is not unreasonable shall be considered agency action for purposes of judicial review under chapter 7 of title 5, United States Code [*5 U.S.C. §§ 701* et seq.]. This subsection shall not take effect until two years after the effective date of this Act [*15 U.S.C. § 2601* effective date note].

(g) PETITION FOR ~~STANDARDS~~PROTOCOLS AND METHODOLOGIES FOR THE DEVELOPMENT OF ~~TEST DATA~~INFORMATION.—A person intending to manufacture or process a chemical substance for which notice is required under section 5(a) [*15 U.S.C. § 2604(a)*] and who is not required under a rule, order, or consent agreement under subsection (a) to conduct tests and submit ~~data~~information on such substance may petition the Administrator to prescribe standards for the development of ~~test data~~information for such substance. The Administrator shall by order either grant or deny any such petition within 60 days of its receipt. If the petition is granted, the Administrator shall prescribe such standards for such substance within 75 days of the date the petition is granted. If the petition is denied, the Administrator shall publish, subject to section 14 [*15 U.S.C. § 2613*], in the Federal Register the reasons for such denial.

(h) REDUCTION OF TESTING ON VERTEBRATES.—

(1) IN GENERAL.—The Administrator shall reduce and replace, to the extent practicable, scientifically justified, and consistent with the policies of this title, the use of vertebrate animals in the testing of chemical substances or mixtures under this title by—

(A) prior to making a request or adopting a requirement for testing using vertebrate animals, and in accordance with subsection (a)(3), taking into consideration, as appropriate and to the extent practicable and scientifically justified, reasonably available existing information, including—

(i) toxicity information;

(ii) computational toxicology and bioinformatics; and

(iii) high-throughput screening methods and the prediction models of those methods; and

(B) encouraging and facilitating—

(i) the use of scientifically valid test methods and strategies that reduce or re place the use of vertebrate animals while providing information of equivalent or better scientific quality and relevance that will support regulatory decisions under this title;

(ii) the grouping of 2 or more chemical substances into scientifically appropriate categories in cases in which testing of a chemical substance would provide scientifically valid and useful information on other chemical substances in the category; and

(iii) the formation of industry consortia to jointly conduct testing to avoid unnecessary duplication of tests, provided that such consortia make all information from such testing available to the Administrator.

(2) IMPLEMENTATION OF ALTERNATIVE TESTING METHODS.—To promote the development and timely incorporation of new scientifically valid test methods and strategies that are not based on vertebrate animals, the Administrator shall—

(A) not later than 2 years after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, develop a strategic plan to promote the development and implementation of alternative test methods and strategies to reduce, refine, or replace vertebrate animal testing and provide information of equivalent or better scientific quality and relevance for assessing risks of injury to health or the environment of chemical substances or mixtures through, for example—

(i) computational toxicology and bioinformatics;

(ii) high-throughput screening methods;

(iii) testing of categories of chemical substances;

(iv) tiered testing methods;

(v) in vitro studies;

(vi) systems biology;

(vii) new or revised methods identified by validation bodies such as the Interagency Coordinating Committee on the Validation of Alternative Methods or the Organization for Economic Cooperation and Development; or

(viii) industry consortia that develop information submitted under this title;

(B) as practicable, ensure that the strategic plan developed under subparagraph (A) is reflected in the development of requirements for testing under this section;

(C) include in the strategic plan developed under subparagraph (A) a list, which the Administrator shall update on a regular basis, of particular alternative test methods or strategies the Administrator has identified that do not require new vertebrate animal testing and are scientifically reliable, relevant, and capable of providing information of equivalent or

better scientific reliability and quality to that which would be obtained from vertebrate animal testing;

(D) provide an opportunity for public notice and comment on the contents of the plan developed under subparagraph (A), including the criteria for considering scientific reliability and relevance of the test methods and strategies that may be identified pursuant to subparagraph (C);

(E) beginning on the date that is 5 years after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, and every 5 years thereafter, submit to Congress a report that describes the progress made in implementing the plan developed under subparagraph (A) and goals for future alternative test methods and strategies implementation; and

(F) prioritize and, to the extent consistent with available resources and the Administrator's other responsibilities under this title, carry out performance assessment, validation, and translational studies to accelerate the development of scientifically valid test methods and strategies that reduce, refine, or replace the use of vertebrate animals, including minimizing duplication, in any testing under this title.

(3) VOLUNTARY TESTING.—

(A) IN GENERAL.—Any person developing information for submission under this title on a voluntary basis and not pursuant to any request or requirement by the Administrator shall first attempt to develop the information by means of an alternative test method or strategy identified by the Administrator pursuant to paragraph (2)(C), if the Administrator has identified such a test method or strategy for the development of such information, before conducting new vertebrate animal testing.

(B) EFFECT OF PARAGRAPH.—Nothing in this paragraph shall, under any circumstance, limit or restrict the submission of any existing information to the Administrator.

(C) RELATIONSHIP TO OTHER LAW.—A violation of this paragraph shall not be a prohibited act under section 15.

(D) REVIEW OF MEANS.—This paragraph authorizes, but does not require, the Administrator to review the means by which a person conducted testing described in subparagraph 2 (A).

SEC. 5 [§ 2604]. MANUFACTURING AND PROCESSING NOTICES

(a) IN GENERAL.—

(1) (A) Except as provided in subparagraph (B) of this paragraph and subsection (h), no person may—

(~~A~~i) manufacture a new chemical substance on or after the 30th day after the date on which the Administrator first publishes the list required by section 8(b) [*15 U.S.C. § 2607(b)*], or

(~~B~~ii) manufacture or process any chemical substance for a use which the Administrator has determined, in accordance with paragraph (2), is a significant new use~~,~~.

~~unless such person submits to the Administrator, at least 90 days before such manufacture or processing, a notice, in accordance with subsection (d), of such person's intention to manufacture or process such substance and such person complies with any applicable requirement of subsection (b).~~

(B) A person may take the actions described in subparagraph (A) if—

(i) such person submits to the Administrator, at least 90 days before such manufacture or processing, a notice, in accordance with subsection (d), of such person's intention to manufacture or process such substance and such person complies with any applicable requirement of, or imposed pursuant to, subsection (b), (e), or (f); and

(ii) the Administrator—

(I) conducts a review of the notice; and

(II) makes a determination under subparagraph (A), (B), or (C) of paragraph (3) and takes the actions required in association with that determination under such subparagraph within the applicable review period.

(3) REVIEW AND DETERMINATION.—Within the applicable review period, subject to section 18, the Administrator shall review such notice and determine—

(A) that the relevant chemical substance or significant new use presents an unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by the Administrator under the conditions of use, in which case the Administrator shall take the actions required under subsection (f);

(B) that—

(i) the information available to the Administrator is insufficient to permit a reasoned evaluation of the health and environmental effects of the relevant chemical substance or significant new use; or

(ii)(I) in the absence of sufficient information to permit the Administrator to make such an evaluation, the manufacture, processing, distribution in commerce, use, or disposal of such substance, or any combination of such activities, may present an unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by the Administrator; or

(II) such substance is or will be produced in substantial quantities, and such substance either enters or may reasonably be anticipated to enter the environment in substantial quantities or there is or may be significant or substantial human exposure to the substance,

in which case the Administrator shall take the actions required under subsection (e);

(C) that the relevant chemical substance or significant new use is likely not to present an unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by the Administrator under the conditions of use, in which case the submitter of the notice may commence manufacture of the chemical substance or manufacture or processing for a significant new use; or

(4) FAILURE TO RENDER DETERMINATION.—

(A) FAILURE TO RENDER DETERMINATION.—If the Administrator fails to make a determination on a notice under paragraph (3) by the end of the applicable review period and the notice has not been withdrawn by the submitter, the Administrator shall refund to the submitter all applicable fees charged to the submitter for review of the notice pursuant to section 26(b), and the Administrator shall not be relieved of any requirement to make such determination.

(B) LIMITATIONS.—(i) A refund of applicable fees under subparagraph (A) shall not be made if the Administrator certifies that the submitter has not provided information required under subsection (b) or has otherwise unduly delayed the process such that the Administrator is unable to render a determination within the applicable review period.

(ii) A failure of the Administrator to render a decision shall not be deemed to constitute a withdrawal of the notice.

(iii) Nothing in this paragraph shall be construed as relieving the Administrator or the submitter of the notice from any requirement of this section.

(5) ARTICLE CONSIDERATION.—The Administrator may require notification under this section for the import or processing of a chemical substance as part of an article or category of articles under paragraph (1)(A)(ii) if the Administrator makes an affirmative finding in a rule under paragraph (2) that the reasonable potential for exposure to the chemical substance through the article or category of articles subject to the rule justifies notification.

(2) A determination by the Administrator that a use of a chemical substance is a significant new use with respect to which notification is required under paragraph (1) shall be made by a rule promulgated after a consideration of all relevant factors, including—

(A) the projected volume of manufacturing and processing of a chemical substance,

(B) the extent to which a use changes the type or form of exposure of human beings or the environment to a chemical substance,

(C) the extent to which a use increases the magnitude and duration of exposure of human beings or the environment to a chemical substance, and

(D) the reasonably anticipated manner and methods of manufacturing, processing, distribution in commerce, and disposal of a chemical substance.

(b) SUBMISSION OF ~~TEST DATA~~INFORMATION.—

(1) (A) If (i) a person is required by subsection (a)(1) to submit a notice to the Administrator before beginning the manufacture or processing of a chemical substance, and (ii) such person is required to submit ~~test data~~information for such substance pursuant to a rule, order, or consent agreement ~~promulgated~~ under section 4 [*15 U.S.C. § 2603*] before the submission of such notice, such person shall submit to the Administrator such ~~data~~ information in accordance with such rule, order, or consent agreement at the time notice is submitted in accordance with subsection (a)(1).

(B) If—

(i) a person is required by subsection (a)(1) to submit a notice to the Administrator, and

(ii) such person has been granted an exemption under section 4(c) [*15 U.S.C. § 2603(c)*] from the requirements of a rule or order ~~promulgated~~ under section 4 [*15 U.S.C. § 2603*] before the submission of such notice,

such person may not, before the expiration of the 90 day period which begins on the date of the submission in accordance with such rule of the ~~test data~~information the submission or development of which was the basis for the exemption, manufacture such substance if such person is subject to subsection (a)(1)(A)(i) or manufacture or process such substance for a significant new use if the person is subject to subsection (a)(1)(~~B~~A)(ii).

(2) (A) If a person—

(i) is required by subsection (a)(1) to submit a notice to the Administrator before beginning the manufacture or processing of a chemical substance listed under paragraph (4), and

(ii) is not required by a rule, order, or consent agreement ~~promulgated~~ under section 4 [*15 U.S.C. § 2603*] before the submission of such notice to submit ~~test data~~information for such substance,

such person ~~shall~~may submit to the Administrator ~~data~~ information prescribed by subparagraph (B) at the time notice is submitted in accordance with subsection (a)(1).

(B) ~~Data~~Information submitted pursuant to subparagraph (A) shall be ~~data~~ information which the person submitting the ~~data~~ information believes shows that—

(i) in the case of a substance with respect to which notice is required under subsection (a)(1)(A)(i), the manufacture, processing, distribution in commerce, use, and disposal of the chemical substance or any combination of such activities will not present an unreasonable risk of injury to health or the environment, or

(ii) in the case of a chemical substance with respect to which notice is required under subsection (a)(1)(~~B~~A)(ii), the intended significant new use of the chemical substance will not present an unreasonable risk of injury to health or the environment.

(3) ~~Data~~ Information submitted under paragraph (1) or (2) of this subsection or under subsection (e) shall be made available, subject to section 14 [*15 U.S.C. § 2613*], for examination by interested persons.

(4) (A) (i) The Administrator may, by rule, compile and keep current a list of chemical substances with respect to which the Administrator finds that the manufacture, processing, distribution in commerce, use, or disposal, or any combination of such activities, presents or may present an unreasonable risk of injury to health or the environment without consideration of costs or other nonrisk factors.

(ii) In making a finding under clause (i) that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or any combination of such activities presents or may present an unreasonable risk of injury to health or the environment, the Administrator shall consider all relevant factors, including—

(I) the effects of the chemical substance on health and the magnitude of human exposure to such substance; and

(II) the effects of the chemical substance on the environment and the magnitude of environmental exposure to such substance.

(B) The Administrator shall, in prescribing a rule under subparagraph (A) which lists any chemical substance, identify those uses, if any, which the Administrator determines, by rule under subsection (a)(2), would constitute a significant new use of such substance.

(C) Any rule under subparagraph (A), and any substantive amendment or repeal of such a rule, shall be promulgated pursuant to the procedures specified in *section 553 of title 5, United States Code*, ~~except that (i) the Administrator shall give interested persons an opportunity for the oral presentation of data, views, or arguments, in addition to an opportunity to make written submissions, (ii) a transcript shall be kept of any oral presentation, and (iii) the Administrator shall make and publish with the rule the finding described in~~ subparagraph (A).

(c) EXTENSION OF ~~NOTICE~~ REVIEW PERIOD.—The Administrator may for good cause extend for additional periods (not to exceed in the aggregate 90 days) the period, prescribed by subsection (a) or (b) ~~before which the manufacturing or processing of a chemical substance subject to such subsection may begin~~. Subject to section 14 [*15 U.S.C. § 2613*], such an extension and the reasons therefor shall be published in the Federal Register and shall constitute a final agency action subject to judicial review.

(d) CONTENT OF NOTICE; PUBLICATIONS IN THE FEDERAL REGISTER.—

(1) The notice required by subsection (a) shall include—

(A) insofar as known to the person submitting the notice or insofar as reasonably ascertainable, the information described in subparagraphs (A), (B), (C), (D), (F), and (G) of section 8(a)(2) [*15 U.S.C. § 2607(a)(2)(A)*-(D), (F), and (G)], and

(B) in such form and manner as the Administrator may prescribe, any ~~test data~~information in the possession or control of the person giving such notice which are related to the effect of any manufacture, processing, distribution in commerce, use, or disposal of such substance or any article containing such substance, or of any combination of such activities, on health or the environment, and

(C) a description of any other ~~data~~ information concerning the environmental and health effects of such substance, insofar as known to the person making the notice or insofar as reasonably ascertainable.

Such a notice shall be made available, subject to section 14 [*15 U.S.C. § 2613*], for examination by interested persons.

(2) Subject to section 14 [*15 U.S.C. § 2613*], not later than five days (excluding Saturdays, Sundays and legal holidays) after the date of the receipt of a notice under subsection (a) or of data under subsection (b), the Administrator shall publish in the Federal Register a notice which—

(A) identifies the chemical substance for which notice or ~~data~~ information has been received;

(B) lists the uses ~~or intended uses~~ of such substance identified in the notice; and

(C) in the case of the receipt of ~~data~~ information under subsection (b), describes the nature of the tests performed on such substance and any ~~data~~ information which was developed pursuant to subsection (b) or a rule, order, or consent agreement under section 4 [*15 U.S.C. § 2603*].

A notice under this paragraph respecting a chemical substance shall identify the chemical substance by generic class unless the Administrator determines that more specific identification is required in the public interest.

(3) At the beginning of each month the Administrator shall publish a list in the Federal Register of

(A) each chemical substance for which notice has been received under subsection (a) and for which the ~~notification~~ applicable review period ~~prescribed by subsection (a), (b), or (c)~~ has not expired, and

(B) each chemical substance for which such ~~notification~~ period has expired since the last publication in the Federal Register of such list.

(e) REGULATION PENDING DEVELOPMENT OF INFORMATION.—

(1)(A) If the Administrator determines that—

(i) the information available to the Administrator is insufficient to permit a reasoned evaluation of the health and environmental effects of a chemical substance with respect to which notice is required by subsection (a); ~~and~~or

(ii) (I) in the absence of sufficient information to permit the Administrator to make such an evaluation, the manufacture, processing, distribution in commerce, use, or disposal of such substance, or any combination of such activities, may present an unreasonable risk of injury to health or the environment without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed subpopulation identified as relevant by the Administrator under the conditions of use;~~,~~ or

(II) such substance is or will be produced in substantial quantities, and such substance either enters or may reasonably be anticipated to enter the environment in substantial quantities or there is or may be significant or substantial human exposure to the substance,

the Administrator ~~may~~ shall issue ~~a proposed~~an order, to take effect on the expiration of the ~~notification period applicable to the manufacturing or processing of such substance under subsection (a), (b), or (c)~~applicable review period, to prohibit or limit the manufacture, processing, distribution in commerce, use, or disposal of such substance or to prohibit or limit any combination of such activities to the extent necessary to protect against an unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by the Administrator under the conditions of use, and the submitter of the notice may commence manufacture of the chemical substance, or manufacture or processing of the chemical substance for a significant new use, including while any required information is being developed, only in compliance with the order.

(B) ~~A proposed~~An order may not be issued under subparagraph (A) respecting a chemical substance (i) later than 45 days before the expiration of the ~~notification period applicable to the manufacture or processing of such substance under subsection (a), (b), or (c)~~applicable review period, and (ii) unless the Administrator has, on or before the issuance of the ~~proposed~~ order, notified, in writing, each manufacturer or processor, as the case may be, of such substance of the determination which underlies such order.

~~(C) If a manufacturer or processor of a chemical substance to be subject to a proposed order issued under subparagraph (A) files with the Administrator (within the 30-day period beginning on the date such manufacturer or processor received the notice required by subparagraph (B)(ii)) objections specifying with particularity the provisions of the order deemed objectionable and stating the grounds therefor, the proposed order shall not take effect.~~

~~(2) (A) (i) Except as provided in clause (ii), if with respect to a chemical substance with respect to which notice is required by subsection (a), the Administrator makes the determination described in paragraph (1)(A) and if—~~

~~(I) the Administrator does not issue a proposed order under paragraph (1) respecting such substance, or~~

(II) the Administrator issues such an order respecting such substance but such order does not take effect because objections were filed under paragraph (1)(C) with respect to it, the Administrator, through attorneys of the Environmental Protection Agency, shall apply to the United States District Court for the District of Columbia or the United States district court for the judicial district in which the manufacturer or processor, as the case may be, of such substance is found, resides, or transacts business for an injunction to prohibit or limit the manufacture, processing, distribution in commerce, use, or disposal of such substance (or to prohibit or limit any combination of such activities).

(ii) If the Administrator issues a proposed order under paragraph (1)(A) respecting a chemical substance but such order does not take effect because objections have been filed under paragraph (1)(C) with respect to it, the Administrator is not required to apply for an injunction under clause (i) respecting such substance if the Administrator determines, on the basis of such objections, that the determinations under paragraph (1)(A) may not be made.

(B) A district court of the United States which receives an application under subparagraph (A)(i) for an injunction respecting a chemical substance shall issue such injunction if the court finds that—

(i) the information available to the Administrator is insufficient to permit a reasoned evaluation of the health and environmental effects of a chemical substance with respect to which notice is required by subsection (a); and

(ii) (I) in the absence of sufficient information to permit the Administrator to make such an evaluation, the manufacture, processing, distribution in commerce, use, or disposal of such substance, or any combination of such activities, may present an unreasonable risk of injury to health or the environment, or

(II) such substance is or will be produced in substantial quantities, and such substance either enters or may reasonably be anticipated to enter the environment in substantial quantities or there is or may be significant or substantial human exposure to the substance.

(C) Pending the completion of a proceeding for the issuance of an injunction under subparagraph (B) respecting a chemical substance, the court may, upon application of the Administrator made through attorneys of the Environmental Protection Agency, issue a temporary restraining order or a preliminary injunction to prohibit the manufacture, processing, distribution in commerce, use, or disposal of such a substance (or any combination of such activities) if the court finds that the notification period applicable under subsection (a), (b), or (c) to the manufacturing or processing of such substance may expire before such proceeding can be completed.

(D) After the submission to the Administrator of test data sufficient to evaluate the health and environmental effects of a chemical substance subject to an injunction issued under subparagraph (B) and the evaluation of such data by the Administrator, the district court of the United States which issued such injunction shall, upon petition, dissolve the injunction unless the Administrator has initiated a proceeding for the issuance of a rule under section 6(a) [*15 U.S.C. § 2605(a)*] respecting the substance. If such a proceeding has been initiated, such court shall continue the injunction in effect until the effective date of the rule promulgated in such proceeding or, if such proceeding is terminated without the promulgation of a rule, upon the termination of the proceeding, whichever occurs first.

(f) PROTECTION AGAINST UNREASONABLE RISKS.—

(1) If the Administrator ~~finds that there is a reasonable basis to conclude that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance~~determines that a chemical substance or significant new use with respect to which notice is required by subsection (a), ~~or that any combination of such activities,~~ presents or will present an unreasonable risk of injury to health or environment, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed subpopulation identified as relevant by the Administrator under the conditions of use, ~~before a rule promulgated under section 6 [*15 U.S.C. § 2605*] can protect against such risk,~~ the Administrator shall, before the expiration of the ~~notification period applicable under subsection (a), (b), or (c) to the manufacturing or processing of such substance~~applicable review period, take the action authorized by paragraph (2) or (3) to the extent necessary to protect against such risk.

(2) The Administrator may issue a proposed rule under section 6(a) [*15 U.S.C. § 2605(a)*] to apply to a chemical substance with respect to which a finding was made under paragraph (1)—

(A) a requirement limiting the amount of such substance which may be manufactured, processed, or distributed in commerce,

(B) a requirement described in paragraph (2), (3), (4), (5), (6), or (7) of section 6(a) [*15 U.S.C. § 2605(a)(2)*, (3), (4), (5), (6), or (7)], or

(C) any combination of the requirements referred to in subparagraph (B).

Such a proposed rule shall be effective upon its publication in the Federal Register. Section 6(d)(~~2~~3)(B) [*15 U.S.C. § 2605(d)(2)(B)*] shall apply with respect to such rule.

(3) (A) The Administrator may—

(i) issue an ~~proposed~~ order to prohibit or limit the manufacture, processing, or distribution in commerce of a substance with respect to which a finding was made ~~under paragraph (1), or~~under paragraph (1). Such order shall take effect on the expiration of the applicable review period.

~~(ii) apply, through attorneys of the Environmental Protection Agency, to the United States District Court for the District of Columbia or the United States district court for the judicial district in which the manufacturer, or processor, as the case may be, of such substance, is found, resides, or transacts business for an injunction to prohibit the manufacture, processing, or distribution in commerce of such substance.~~

~~A proposed order issued under clause (i) respecting a chemical substance shall take effect on the expiration of the notification period applicable under subsection (a), (b), or (c) to the manufacture or processing of such substance.~~

~~(B) If the district court of the United States to which an application has been made under subparagraph (A)(ii) finds that there is a reasonable basis to conclude that the manufacture, processing, distribution in commerce, use, or disposal of the chemical substance with respect to which such application was made, or that any combination of such activities, presents or will present an unreasonable risk of injury to health or the environment before a rule promulgated under section 6 [*15 U.S.C. § 2605*] can protect against such risk, the court shall issue an injunction to prohibit the manufacture, processing, or distribution in commerce of such substance or to prohibit any combination of such activities.~~

(~~C~~B) The provisions of subparagraphs (B) ~~and (C)~~ of subsection (e)(1) shall apply with respect to an order issued under ~~clause (i) of~~ subparagraph (A)~~; and the provisions of subparagraph (C) of subsection (e)(2) shall apply with respect to an injunction issued under subparagraph (B).~~

~~(D) If the Administrator issues an order pursuant to subparagraph (A)(i) respecting a chemical substance and objections are filed in accordance with subsection (e)(1)(C), the Administrator shall seek an injunction under subparagraph (A)(ii) respecting such substance unless the Administrator determines, on the basis of such objections, that such substance does not or will not present an unreasonable risk of injury to health or the environment~~.

(4) TREATMENT OF NONCONFORMING USES.— Not later than 90 days after taking an action under paragraph (2) or (3) or issuing an order under subsection (e) relating to a chemical substance with respect to which the Administrator has made a determination under subsection (a)(3)(A) or (B), the Administrator shall consider whether to promulgate a rule pursuant to subsection (a)(2) that identifies as a significant new use any manufacturing, processing, use, distribution in commerce, or disposal of the chemical substance that does not conform to the restrictions imposed by the action or order, and, as applicable, initiate such a rulemaking or publish a statement describing the reasons of the Administrator for not initiating such a rulemaking.

(5) WORKPLACE EXPOSURES.—To the extent practicable, the Administrator shall consult with the Assistant Secretary of Labor for Occupational Safety and Health prior to adopting any prohibition or other restriction relating to a chemical substance with respect to which the Administrator has made a determination under subsection (a)(3)(A) or (B) to address workplace exposures.

~~(g) STATEMENT OF REASONS FOR NOT TAKING ACTION.—If the Administrator has not initiated any action under this section or section 6 or 7 [*15 U.S.C. § 2605* or *2606*] to prohibit or limit the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance, with respect to which notification or data is required by subsection (a)(1)(B) or (b), before the expiration of the notification period applicable to the manufacturing or processing of such substance, the Administrator shall publish a statement of the Administrator's reasons for not initiating such action. Such a statement shall be published in the Federal Register before the expiration of such period. Publication of such statement in accordance with the preceding sentence is not a prerequisite to the manufacturing or processing of the substance with respect to which the statement is to be published.~~

(g) STATEMENT ON ADMINISTRATOR FINDING.—If the Administrator finds in accordance with subsection (a)(3)(C) that a chemical substance or significant new use is not likely to present an unreasonable risk of injury to health or the environment, is a low-hazard substance, then notwithstanding any remaining portion of the applicable review period, the submitter of the notice may commence manufacture of the chemical substance or manufacture or processing for the significant new use, and the Administrator shall make public a statement of the Administrator's finding. Such a statement shall be submitted for publication in the Federal Register as soon as is practicable before the expiration of such period. Publication of such statement in accordance with the preceding sentence is not a prerequisite to the manufacturing or

processing of the substance with respect to which the statement is to be published.

(h) EXEMPTIONS.—

(1) The Administrator may, upon application, exempt any person from any requirement of subsection (a) or (b) to permit such person to manufacture or process a chemical substance for test marketing purposes—

(A) upon a showing by such person satisfactory to the Administrator that the manufacture, processing, distribution in commerce, use, and disposal of such substance, and that any combination of such activities, for such purposes will not present any unreasonable risk of injury to health or the environment, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified by the Administrator for the specific conditions of use identified in the application, and

(B) under such restrictions as the Administrator considers appropriate.

(2) (A) The Administrator may, upon application, exempt any person from the requirement of subsection (b)(2) to submit ~~data~~ information for a chemical substance. If, upon receipt of an application under the preceding sentence, the Administrator determines that—

(i) the chemical substance with respect to which such application was submitted is equivalent to a chemical substance for which ~~data~~ information has been submitted to the Administrator as required by subsection (b)(2), and

(ii) submission of ~~data~~ information by the applicant on such substance would be duplicative of data which has been submitted to the Administrator in accordance with such subsection,

the Administrator shall exempt the applicant from the requirement to submit such ~~data~~ information on such substance. No exemption which is granted under this subparagraph with respect to the submission of ~~data~~ information for a chemical substance may take effect before the beginning of the reimbursement period applicable to such ~~data~~information.

(B) If the Administrator exempts any person, under subparagraph (A), from submitting ~~data~~ information required under subsection (b)(2) for a chemical substance because of the existence of previously submitted ~~data~~ information and if such exemption is granted during the reimbursement period for such ~~data~~ information, then (unless such person and the persons referred to in clauses (i) and (ii) agree on the amount and method of reimbursement) the Administrator shall order the person granted the exemption to provide fair and equitable reimbursement (in an amount determined under rules of the Administrator) —

(i) to the person who previously submitted the ~~data~~ information on which the exemption was based, for a portion of the costs incurred by such person in complying with the requirement under subsection (b)(2) to submit such ~~data~~information, and

(ii) to any other person who has been required under this subparagraph to contribute with respect to such costs, for a portion of the amount such person was required to contribute.

In promulgating rules for the determination of fair and equitable reimbursement to the persons described in clauses (i) and (ii) for costs incurred with respect to a chemical substance, the Administrator shall, after consultation with the Attorney General and the Federal Trade Commission, consider all relevant factors, including the effect on the competitive position of the person required to provide reimbursement in relation to the persons to be reimbursed and the share of the market for such substance of the person required to provide reimbursement in relation to the share of such market of the persons to be

reimbursed. For purposes of judicial review, an order under this subparagraph shall be considered final agency action.

(C) For purposes of this paragraph, the reimbursement period for any previously submitted data for a chemical substance is a period—

(i) beginning on the date of the termination of the prohibition, imposed under this section, on the manufacture or processing of such substance by the person who submitted such ~~data~~ information to the Administrator, and

(ii) ending—

(I) five years after the date referred to in clause (i), or

(II) at the expiration of a period which begins on the date referred to in clause (i) and is equal to the period which the Administrator determines was necessary to develop such ~~data~~ information,

whichever is later.

(3) The requirements of subsections (a) and (b) do not apply with respect to the manufacturing or processing of any chemical substance which is manufactured or processed, or proposed to be manufactured or processed, only in small quantities (as defined by the Administrator by rule) solely for purposes of—

(A) scientific experimentation or analysis, or

(B) chemical research on, or analysis of such substance or another substance, including such research or analysis for the development of a product,

if all persons engaged in such experimentation, research, or analysis for a manufacturer or processor are notified (in such form and manner as the Administrator may prescribe) of any risk to health which the manufacturer, processor, or the Administrator has reason to believe may be associated with such chemical substance.

(4) The Administrator may, upon application and by rule, exempt the manufacturer of any new chemical substance from all or part of the requirements of this section if the Administrator determines that the manufacture, processing, distribution in commerce, use, or disposal of such chemical substance, or that any combination of such activities, will not present an unreasonable risk of injury to health or the environment, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified by the Administrator under the conditions of use. ~~A rule promulgated under this paragraph (and any substantive amendment to, or repeal of, such a rule) shall be promulgated in accordance with paragraphs (2) and (3) of section 6(c) [*15 U.S.C. § 2605(c)(2)* and (3)].~~

(5) The Administrator may, upon application, make the requirements of subsections (a) and (b) inapplicable with respect to the manufacturing or processing of any chemical substance

(A) which exists temporarily as a result of a chemical reaction in the manufacturing or processing of a mixture or another chemical substance, and

(B) to which there is no, and will not be, human or environmental exposure.

(6) Immediately upon receipt of an application under paragraph (1) or (5) the Administrator shall publish in the Federal Register notice of the receipt of such application. The Administrator shall give interested persons an opportunity to comment upon any such application and shall,

within 45 days of its receipt, either approve or deny the application. The Administrator shall publish in the Federal Register notice of the approval or denial of such an application.

~~(i) DEFINITION.—For purposes of this section, the terms "manufacture" and "process" mean manufacturing or processing for commercial purposes.~~
(i) DEFINITIONS.—(1) For purposes of this section, the terms 'manufacture' and 'process' mean manufacturing or processing for commercial purposes.

(2) For purposes of this Act, the term 'requirement' as used in this section shall not displace any statutory or common law.

(3) For purposes of this section, the term 'applicable review period' means the period starting on the date the Administrator receives a notice under subsection (a)(1) and ending 90 days after that date, or on such date as is provided for in subsection (b)(1) or (c).

SEC. 6 [§ 2605]. ~~REGULATION OF HAZARDOUS CHEMICAL SUBSTANCES AND MIXTURES~~ PRIORITIZATION, RISK EVALUATION, AND REGULATION OF CHEMICAL SUBSTANCES AND MIXTURES

(a) SCOPE OF REGULATION.—If the Administrator ~~finds that there is a reasonable basis to conclude~~ determines in accordance with subsection (b)(4)(A) that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or mixture, or that any combination of such activities, presents ~~or will present~~ an unreasonable risk of injury to health or the environment, the Administrator shall by rule and subject to section 18, and in accordance with subsection (c)(2) apply one or more of the following requirements to such substance or mixture to the extent necessary ~~to protect adequately against such risk using the least burdensome requirements~~ so that the chemical substance or mixture no longer presents such risk:

(1) A requirement (A) prohibiting or otherwise restricting the manufacturing, processing, or distribution in commerce of such substance or mixture, or (B) limiting the amount of such substance or mixture which may be manufactured, processed, or distributed in commerce.

(2) A requirement—
(A) prohibiting or otherwise restricting the manufacture, processing, or distribution in commerce of such substance or mixture for (i) a particular use or (ii) a particular use in a concentration in excess of a level specified by the Administrator in the rule imposing the requirement, or
(B) limiting the amount of such substance or mixture which may be manufactured, processed, or distributed in commerce for (i) a particular use or (ii) a particular use in a concentration in excess of a level specified by the Administrator in the rule imposing the requirement.

(3) A requirement that such substance or mixture or any article containing such substance or mixture be marked with or accompanied by clear and adequate minimum warnings and instructions with respect to its use, distribution in commerce, or disposal or with respect to any

combination of such activities. The form and content of such minimum warnings and instructions shall be prescribed by the Administrator.

(4) A requirement that manufacturers and processors of such substance or mixture make and retain records of the processes used to manufacture or process such substance or mixture ~~and~~ or monitor or conduct tests which are reasonable and necessary to assure compliance with the requirements of any rule applicable under this subsection.

(5) A requirement prohibiting or otherwise regulating any manner or method of commercial use of such substance or mixture.

(6) (A) A requirement prohibiting or otherwise regulating any manner or method of disposal of such substance or mixture, or of any article containing such substance or mixture, by its manufacturer or processor or by any other person who uses, or disposes of, it for commercial purposes.
(B) A requirement under subparagraph (A) may not require any person to take any action which would be in violation of any law or requirement of, or in effect for, a State or political subdivision, and shall require each person subject to it to notify each State and political subdivision in which a required disposal may occur of such disposal.

(7) A requirement directing manufacturers or processors of such substance or mixture (A) to give notice of such ~~unreasonable risk of injury~~ determination to distributors in commerce of such substance or mixture and, to the extent reasonably ascertainable, to other persons in possession of such substance or mixture or exposed to such substance or mixture, (B) to give public notice of such ~~risk of injury~~determination, and (C) to replace or repurchase such substance or mixture as elected by the person to which the requirement is directed.

Any requirement (or combination of requirements) imposed under this subsection may be limited in application to specified geographic areas.

~~(b) QUALITY CONTROL.—If the Administrator has a reasonable basis to conclude that a particular manufacturer or processor is manufacturing or processing a chemical substance or mixture in a manner which unintentionally causes the chemical substance or mixture to present or which will cause it to present an unreasonable risk of injury to health or the environment—~~

~~—(1) the Administrator may by order require such manufacturer or processor to submit a description of the relevant quality control procedures followed in the manufacturing or processing of such chemical substance or mixture; and~~

~~—(2) if the Administrator determines—~~

~~—(A) that such quality control procedures are inadequate to prevent the chemical substance or mixture from presenting such risk of injury, the Administrator may order the manufacturer or processor to revise such quality control procedures to the extent necessary to remedy such inadequacy; or~~

~~(B) that the use of such quality control procedures has resulted in the distribution in commerce of chemical substances or mixtures which present an unreasonable risk of injury to health or the environment, the Administrator may order the manufacturer or processor to (i) give notice of such risk to processors or distributors in commerce of any such substance or mixture, or to both, and, to the extent reasonably ascertainable, to any other person in possession of or exposed to any such substance, (ii) to give public notice of such risk, and (iii) to provide such replacement or repurchase of any such substance or mixture as is necessary to adequately protect health or the environment.~~

~~A determination under subparagraph (A) or (B) of paragraph (2) shall be made on the record after opportunity for hearing in accordance with *section 554 of title 5, United States Code*. Any manufacturer or processor subject to a requirement to replace or repurchase a chemical substance or mixture may elect either to replace or repurchase the substance or mixture and shall take either such action in the manner prescribed by the Administrator.~~

~~(b)~~ (b) RISK EVALUATIONS.—(1) PRIORITIZATION FOR RISK EVALUATIONS.—

(A) ESTABLISHMENT OF PROCESS.—Not later than 1 year after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, the Administrator shall establish, by rule, a risk-based screening process, including criteria for designating chemical substances as high-priority substances for risk evaluations or low-priority substances for which risk evaluations are not warranted at the time. The process to designate the priority of chemical substances shall include a consideration of the hazard and exposure potential of a chemical substance or a category of chemical substances(including consideration of persistence and bioaccumulation, potentially exposed or susceptible subpopulations and storage near significant sources of drinking water), the conditions of user significant changes in the conditions of use of the chemical substance, and the volume or significant changes in the volume of the chemical substance manufactured or processed.

(B) IDENTIFICATION OF PRIORITIES FOR RISK EVALUATION.—

(i) HIGH-PRIORITY SUBSTANCES.—

The Administrator shall designate as high-priority substance a chemical substance that the Administrator concludes, without consideration of costs or other nonrisk factors, may present an unreasonable risk of injury to health or the environment because of a potential hazard and a potential route of exposure under the conditions of use, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by the Administrator.

(ii) LOW-PRIORITY SUBSTANCES.—

The Administrator shall designate a chemical substance as a low-priority substance if the Administrator concludes, based on information sufficient to establish, without consideration of costs or other nonrisk factors, that such substance does not meet the standard identified in clause (i) for designating a chemical substance a high-priority substance.

(C) INFORMATION REQUEST AND REVIEW AND PROPOSED AND FINAL PRIORITIZATION DESIGNATION.—

The rulemaking required in subparagraph (A) shall ensure that the time required to make a priority designation of alchemical substance be no shorter than nine months and no longer than 1 year, and that the process for such designations includes—

(i) a requirement that the Administrator request interested persons to submit relevant information on a chemical substance that the Administrator has initiated the prioritization process on, before proposing a priority designation for the chemical substance, and provide 90 days for such information to be provided;

(ii) a requirement that the Administrator publish each proposed designation oaf chemical substance as a high- or low-priority substance, along with an identification of the information, analysis, and basis used to make the proposed designations, and provide 90 days for public comment on each such proposed designation; and

(iii) a process by which the Administrator may extend the deadline in clause(i) for up to three months in order to receive or evaluate information required to be submitted in accordance with section 4(a)(2)(B), subject to the limitation that if the information available to the Administrator at the end of such an extension remains insufficient to enable the designation of the chemical substance as a low-priority substance, the Administrator shall designate the chemical substance as high-priority substance.

(2) INITIAL RISK EVALUATIONS AND SUBSEQUENT DESIGNATIONS OF HIGH- AND LOW-PRIORITY SUBSTANCES.—

(A) INITIAL RISK EVALUATIONS.—Not later than 180 days after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, the Administrator shall ensure that risk evaluations are being conducted on 10 chemical substances drawn from the 2014 update of the TSCA Work Plan for Chemical Assessments and shall publish the list of such chemical substances during the 180 day period.

(B) ADDITIONAL RISK EVALUATIONS.—Not later than three and one half years after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, the Administrator shall ensure that risk evaluations are being conducted on at least 20 high priority substances and that at least 20 chemical substances have been designated as low-priority or low-hazard substances, subject to the limitation that at least 50 percent of all chemical substances on which risk evaluations are being conducted by the Administrator are drawn from the 2014 update of the TSCA Work Plan for Chemical Assessments.

(C) CONTINUING DESIGNATIONS AND RISK EVALUATIONS.—The Administrator shall continue to designate priority substances and conduct risk evaluations in accordance with this subsection at a pace consistent with the ability of the Administrator to complete risk evaluations in accordance with the deadlines under paragraph (4)(G).

(D) PREFERENCE.—In designating high-priority substances, the Administrator shall give preference to—

(i) chemical substances that are listed in the 2014 update of the TSCA Work Plan for Chemical Assessments as having persistence and Bioaccumulation Score of; and

(ii) chemical substances that are listed in the 2014 update of the TSCA Work Plan for Chemical Assessments that are known human carcinogens and have high acute and chronic toxicity.

(E) METALS AND METAL COMPOUNDS.—In identifying priorities for risk evaluation and conducting risk evaluations of metals and metal compounds, the Administrator shall use the Framework for Metals Risk Assessment of the Office of the Science Advisor, Risk Assessment Forum, and dated March 2007, or a successor document that addresses metals risk assessment and is peer reviewed by the Science Advisory Board.

(3) INITIATION OF RISK EVALUATIONS; DESIGNATIONS.—

(A) RISK EVALUATION INITIATION.—Upon designating a chemical substance as high-priority substance, the Administrator shall initiate a risk evaluation on the substance.

(B) REVISION.—The Administrator may revise the designation of a low-priority substance based on information made available to the Administrator.

(C) ONGOING DESIGNATIONS.—The Administrator shall designate at least one high priority substance upon the completion of each risk evaluation (other than risk evaluations for chemical substances designated under pare graph (4)(C)(ii)).

(4) RISK EVALUATION PROCESS AND DEAD-LINES.—

(A) IN GENERAL.—The Administrator shall conduct risk evaluations pursuant to this paragraph to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of costs or other no risk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant to the risk evaluation by the Administrator, under the conditions of use.

(B) ESTABLISHMENT OF PROCESS.—Not later than 1 year after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, the Administrator shall establish, by rule, a process to conduct risk evaluations in accordance with subparagraph 9 (A).

(C) REQUIREMENT.—The Administrator shall conduct and publish risk evaluations, in accordance with the rule promulgated under subparagraph (B), for a chemical substance—
(i) that has been identified under paragraph (2)(A) or designated under paragraph (1)(B)(i); and

(ii) subject to subparagraph (E),that a manufacturer of the chemical substance has requested, in a form and manner and using the criteria prescribed by the Administrator in the rule promulgated under subparagraph (B), be subjected to a risk evaluation.

(D) SCOPE.—The Administrator shall, not later than 6 months after the initiation of a risk evaluation, publish the scope of the risk evaluation to be conducted, including the hazards,

exposures, conditions of use, and the potentially exposed or susceptible subpopulations the Administrator expects to consider, and, for each designation of a high-priority substance, ensure not less than 12 months between the initiation of the prioritization process for the chemical substance and the publication of the scope of the risk evaluation for the chemical substance, and for risk evaluations conducted on chemical substances that have been identified under paragraph (2)(A) or selected under subparagraph (E)(iv)(II) of this paragraph, ensure not less than 3 months before the Administrator publishes the scope of the risk evaluation.

(E) LIMITATION AND CRITERIA.—

(i) PERCENTAGE REQUIREMENTS.—The Administrator shall ensure that, of the number of chemical substances that undergo a risk evaluation under clause (i) of subparagraph (C), the number of chemical substances undergoing a risk evaluation under clause (ii) of subparagraph (C) is—

(I) not less than 25 percent, insufficient requests are made under clause (ii) of subparagraph (C); and

(II) not more than 50 percent.

(ii) REQUESTED RISK EVALUATIONS.—Requests for risk evaluations under subparagraph (C)(ii) shall be subject to the payment of fees pursuant to section 26(b), and the Administrator shall not expedite or otherwise provide special treatment to such risk evaluations.

(iii) PREFERENCE.—In deciding whether to grant requests under subparagraph (C)(ii), the Administrator shall give preference to requests for risk evaluations on chemical substances for which the Administrator determines that restrictions imposed by 1 or more States have the potential to have a significant impact on interstate commerce or health or the environment.

(iv) EXCEPTIONS.—(I) Chemical substances for which requests have been granted under subparagraph (C)(ii) shall not be subject to section 18(b).

(II) Requests for risk evaluations on chemical substances which are made under subparagraph (C)(ii) and that are drawn from the 2014 update of the TSCA Work Plan for Chemical Assessments shall be granted at the discretion of the Administrator and not be subject to clause (i)(II).

(F) REQUIREMENTS.—In conducting a risk evaluation under this subsection, the Administrator shall—

(i) integrate and assess available information on hazards and exposures for the conditions of use of the chemical substance, including information that is relevant to specific risks of injury to health or the environment and information on potentially exposed or susceptible subpopulations identified as relevant by the Administrator;

(ii) describe whether aggregate or sentinel exposures to a chemical substance under the conditions of use were considered, and the basis for that consideration;

(iii) not consider costs or other nonrisk factors;

(iv) take into account, where relevant, the likely duration, intensity, frequency, and number of exposures under the conditions of use of the chemical substance; and

(v) describe the weight of the scientific evidence for the identified hazard and exposure.

(G) DEADLINES.—The Administrator—

(i) shall complete a risk evaluation for a chemical substance as soon as practicable, but not later than 3 years after the date on which the Administrator initiates the risk evaluation under subparagraph(C); and

(ii) may extend the deadline for a risk evaluation for not more than 6 months.

(H) NOTICE AND COMMENT.—The Administrator shall provide no less than 30 days public notice and an opportunity for comment on a draft risk evaluation prior to publishing final risk evaluation.;

(c) PROMULGATION OF SUBSECTION (a) RULES.—

~~(1) In promulgating any rule under subsection (a) with respect to a chemical substance or mixture, the Administrator shall consider and publish a statement with respect to—~~

~~(A) the effects of such substance or mixture on health and the magnitude of the exposure of human beings to such substance or mixture,~~

~~(B) the effects of such substance or mixture on the environment and the magnitude of the exposure of the environment to such substance or mixture,~~

~~(C) the benefits of such substance or mixture for various uses and the availability of substitutes for such uses, and~~

~~(D) the reasonably ascertainable economic consequences of the rule, after consideration of the effect on the national economy, small business, technological innovation, the environment, and public health.~~

~~If the Administrator determines that a risk of injury to health or the environment could be eliminated or reduced to a sufficient extent by actions taken under another Federal law (or laws) administered in whole or in part by the Administrator, the Administrator may not promulgate a rule under subsection (a) to protect against such risk of injury unless the Administrator finds, in the Administrator's discretion, that it is in the public interest to protect against such risk under this Act [*15 U.S.C. §§ 2601* et seq.]. In making such a finding the Administrator shall consider (i) all relevant aspects of the risk, as determined by the Administrator in the Administrator's discretion, (ii) a comparison of the estimated costs of complying with actions taken under this Act [*15 U.S.C. §§ 2601* et seq.] and under such law (or laws), and (iii) the relative efficiency of actions under this Act [*15 U.S.C. §§ 2601* et seq.] and under such law (or laws) to protect against such risk of injury.~~